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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,750	07/03/2001	James G: Wetmur	Enz-49(P2) (C)	7451
28171 7	590 05/17/2006		EXAMINER	
ENZO BIOCHEM, INC.			LU, FRANK WEI MIN	
	527 MADISON AVENUE (9TH FLOOR) NEW YORK, NY 10022		ART UNIT	PAPER NUMBER
			1634	
			DATE MAILED: 05/17/2006	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
	09/898,750	WETMUR ET AL.				
Office Action Summary	Examiner	Art Unit				
	Frank W Lu	1634				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1) Responsive to communication(s) filed on <u>17 February 2006</u> .						
2a) This action is FINAL . 2b) ☐ This	action is non-final.					
·	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
4)⊠ Claim(s) <u>2-178</u> is/are pending in the application.						
4a) Of the above claim(s) <u>2-5,10,25-116,126,13</u>		is/are withdrawn from				
consideration.						
5) Claim(s) is/are allowed.						
6) Claim(s) 6-9,11-24,117-125,127-132,134-137,1	Claim(s) 6-9,11-24,117-125,127-132,134-137,140,141 and 144-148 is/are rejected.					
Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or	election requirement.					
Application Papers						
9)⊠ The specification is objected to by the Examiner.						
10)⊠ The drawing(s) filed on <u>03 July 2001</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) All b) Some * c) None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
1) Notice of References Cited (PTO-892)	4) Interview Summary	(PTO-413)				
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Da	te				
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 7/2001.	5) Notice of Informal Pa	atent Application (PTO-152)				

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DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II, claims 6-25 and 117-148 and species (5) 1. (claims 9 and 125), species (7) (claims 130-32), species (11) (claims 137 and 140), and species 17 (claim 141) in the reply filed on February 17, 2006 is acknowledged. The traversal is on the ground(s) that "[A]pplicants submit that a search of the subject matter of provisionally elected Group II would likely encompass the subject matter of Group IV, and that this would not constitute a serious burden on the Examiner. Groups II and IV, while patentably distinct from one another, are related to each other by composition. Applicants further respectfully note that the restricted subject matter of provisionally elected Group II shares classification with the restricted subject matter of Group IV, in class 536, subclass 23.1, as set forth in the Restriction Requirement. Therefore, Applicants submit that a search of the subject matter of Groups II and IV would not be burdensome because a search of one Group within the class would likely be inclusive of the other Group in that same class. Applicants further submit that it is likely that a search of the elected subject matter corresponding to provisionally elected Group II would also encompass references directed to methods of using the elected subject matter corresponding to provisionally elected Group II, such as for example references directed to methods of modifying a recipient polydeoxynucleotide duplex or labeling a displacer-recipient complex using the claimed compositions. Applicants further respectfully note that the restricted subject matter of Groups I, III and V share the same classification within the Restriction Requirement, namely in class 435, subclass 6. Therefore, it is likely that a search of one Group within the class would be inclusive of the other Groups in that same class".

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The above arguments have been fully considered and have not been found persuasive toward the withdrawal of the restriction requirement nor persuasive toward the relaxation of same such that Groups I to V will be examined together. First, the restriction is not based on classification of different groups but is dependent on different and distinct searches among different groups (see previous office action). Second, there is a search burden to search both Groups II and IV together. For example, the search required for Group IV such as triplex helix formation in claim 57 is not required for Group II which is required for forming triplex helix (see claim 6). Third, applicant has no evidence to show that "a search of the elected subject matter corresponding to provisionally elected Group II would also encompass references directed to methods of using the elected subject matter corresponding to provisionally elected Group II, such as for example references directed to methods of modifying a recipient polydeoxynucleotide duplex or labeling a displacer-recipient complex using the claimed compositions". Fourth, the examiner notes that, since claim 25 is dependent on claims 57-87, now Group II does not include claim 25 and only contains claims 6-24 and 117-148. Therefore, the requirement is still deemed proper and is therefore made FINAL. Claims 6-9, 11-24, 117-125, 127-132, 134-137, 140, 141, and 144-148 will be examined.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: the inventor, Robin Quartin, changes the

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address with an initial. See 37 CFR 1.52(c).

Specification

3. The disclosure is objected to because of the following informality: since case 09/387,300 now is US Patent No. 6,358,685, applicant is required to update this information in the first sentence of the specification.

Appropriate correction is required.

Claim Objections

4. Claim 6 is objected to because of the following informality: no period should appear after the label of each step, e.g., "a." should be --a)--.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 6-9, 11-24, 117-125, 127-132, 134-137, 140, 141, and 144-148 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

The displacer recited in claims 6-9, 11-24, 117-125, 127-132, 134-137, 140, 141, and 144-148, as written, do not sufficiently distinguish over nucleic acids as they exist naturally because the claim does not particularly point out any non-naturally occurring differences

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between the claimed product and the naturally occurring nucleic acid. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified". See MPEP 2105.

Claim Rejections - 35 USC § 112

- 7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 8. Claim 17, 117-125, 127-132, 134-137, 140, 141, and 144-148 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 9. Claim 17 is rejected as vague and indefinite because targets for detecting is not a modification. Please clarify.
- 10. Claim 117 is rejected as vague and indefinite. Since the claim does not describe how to change at least one nucleotide or a nucleotide sequence in said recipient polynucleotide, it is unclear how said displacer is used to change at least one nucleotide or a nucleotide sequence in said recipient polynucleotide. Please clarify.
- 11. Claim 134 is rejected as vague and indefinite. Since endonuclease is defined as an enzyme that cleaves its nucleic acid substrate at internal sites in the nucleotide sequence, it is unclear how at least one moiety attached to a terminus of the oligo or polynucleotide is related to endonuclease resistance to the terminus. Since exonuclease is defined as an enzyme that breaks

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down nucleic acids only at the ends of polynucleotide chains and thus releasing one nucleotide at a time in sequential order, at least one moiety attached to a terminus of the oligo or polynucleotide appears to be related to exonuclease resistance to the terminus. Please clarify.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 13. Claims 6-8, 16-18, 22, 117-119, 121, 144, and 145 are rejected under 35 U.S.C. 102(e) as being anticipated by Dattagupta (US Patent No. 5,215,889, priority date: November 9, 1989).

Regarding claim 6, since Dattagupta teaches a hairpin probe HNT (see column 12),

Dattagupta discloses an oligo- or polydeoxynucleotide displacer-linker duplex (ie., the hairpin probe HNT) which is capable of initiating branch migration at the end of a recipient polydeoxynucleotide duplex (ie., a duplex formed by 5'-CGTTAA-3' and 3'
ATTATGCTGAGTGATATCCCTCTTCAGACGGCAATT-5') without the prior formation of a stable hybrid with such recipient polydeoxynucleotide duplex, which displacer-linker duplex comprises two strands: a) a displacer strand of which a portion comprises nucleotides complementary to one strand of a recipient polydeoxynucleotide duplex (ie., 5'-

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GGAGAAGTCTGCCGTTAC-3') and a portion (ie., 5'-TAATACGACTGACTATAG-3') which comprises a sequence complementary to and hybridized with a linker strand, and b) a linker strand (ie., 3'-ATTATGCTGAGTGATATC-5') complementary to and hybridized with the displacer strand.

Regarding claim 7, Dattagupta teaches that the displacer-linker duplex can initiate branch migration at a restriction endonuclease cleavage site (ie., 5'-CGTTAA-3' for Mse I site in the duplex formed by 3'-ATTATGCTGAGTGATATCCCTCTTCAGACGGCAATT-5' and 5'-TTAA-3').

Regarding claim 8, Dattagupta teaches that the displacer-linker duplex can hybridize to and initiate branch migration adjacent to a 3' or 5' single stranded extension (ie., 3'-ATTATGCTGAGTGATATCCCTCTTCAGACGGC-5' in the duplex formed by 3'-ATTATGCTGAGTGATATCCCTCTTCAGACGGCAATT-5' and 5'-CGTTAA-3') on the recipient polydeoxynucleotide duplex.

Regarding claims 16-18, Dattagupta teaches that the displacer-linker duplex (ie., the hairpin probe HNT) contains a modification (ie., labeled phosphate at 5' end by phosphorylation) which permits detection of the displacer-recipient hybrid as recited in claim 16 wherein the modification is radioactive label (ie., labeled phosphate) as recited in claim 17 and the modification is present in the linker (5' of the linker, ie., 3'-ATTATGCTGAGTGATATC-5')(see column 12).

Regarding claim 22, since 5'-GGAGAAGTCTGCCGTTAC-3' in the hairpin probe HNT can hybridize to a Mse I digested double stranded nucleic acid having 3' single-stranded AAT extension (see column 12), Dattagupta teaches that the displacer-linker duplex also comprises a

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5' or 3' single-stranded extension (ie., 5'-GGAGAAGTCTGCCGTTAC-3' in the hairpin probe HNT) complementary to a 5' or 3' single-stranded extension (ie., AAT) resulting from the digestion of a polydeoxynucleotide duplex with a restriction endonuclease (ie., Mse I).

Regarding claim 117, Dattagupta teaches a nucleic acid displacer composition which comprises an oligo- or polynucleotide displacer which binds to or complexes with a recipient polynucleotide (ie., a duplex formed by 5'-CGTTAA-3' and 3'-

ATTATGCTGAGTGATATCCCTCTTCAGACGGCAATT-5'), said oligo- or polynucleotide displacer comprising two or more sequences: a) at least one first sequence (ie., 5'-

AGAAGTCTGCCGTTAC-3' from the hairpin probe HNT) which binds or complexes with said recipient polynucleotide; and b) at least one second sequence (ie., 5'

TAATACGACTGACTATAG-3' from the hairpin probe HNT), said second sequence (i) being complementary or identical to at least a portion of said recipient polynucleotide; and (ii) comprising one or more nucleotides which are different (ie., ATCG) wherein said displacer changes at least one nucleotide or a nucleotide sequence in said recipient polynucleotide (ie., C-T mismatch after hybridizing said displacer to said recipient polynucleotide) (see column 12).

Regarding claims 118, 119, and 121, Dattagupta teaches that said second sequence (ie., 5' TAATACGACTGACTATAG-3' from the hairpin probe HNT) is adjacent to said first sequence (ie., 5'AGAAGTCTGCCGTTAC-3' from the hairpin probe HNT) as recited in claim 118, said second sequence is separated from said first sequence by from 1 to 5 intervening moieties.(ie., two nucleotides GG) as recited in claim 119 wherein said intervening moieties are nucleotides as recited in claim 121 (see column 12).

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Regarding claims 144 and 145, Dattagupta teaches that the displacer-linker duplex (ie., the hairpin probe HNT) comprises a modification (ie., labeled phosphate by phosphorylation) which permits detection of the displacer-recipient complex as recited in claim 144 wherein the modification is radioactive label (ie., labeled phosphate) as recited in claim 145 (see column 12).

Therefore, Dattagupta teaches all limitations recited in claims 6-8, 16-18, 22, 117-119, 121, 144, and 145.

14. Claims 23, 24, and 148 are rejected under 35 U.S.C. 102(b) as being anticipated by Maniatis *et al.*, (Cell, 15, 687-701, 1978).

Regarding claim 23, since Maniatis et al., teach to clone EcoRI digested 20 kb eukaryotic genomic DNA into EcoRI digested charon 4A vector (see Figure 1 in page 688) and the DNA fragment digested with EcoRI has 4 bp cohesive ends, Maniatis et al., disclose an artificially constructed polydeoxynucleotide hybrid comprising a naturally occurring recipient polydeoxynucleotide duplex (ie., EcoRI digested 20 kb eukaryotic genomic DNA having 4 bp cohesive ends) hybridized to the displacer-linker duplex of any of claims 6-22 (ie., EcoRI digested charon 4A vector having 4 bp cohesive ends). Note that, since a recipient polydeoxynucleotide duplex is not a component of claim 6 and the EcoRI digested charon 4A vector taught by Maniatis et al., has an ability to initiate branch migration at the end of a recipient polydeoxynucleotide duplex which exists in nature and is different from the recipient polydeoxynucleotide duplex recited in claim 23 without the prior formation of a stable hybrid with such recipient polydeoxynucleotide duplex, the EcoRI digested charon 4A vector taught by Maniatis et al., is an oligo- or polydeoxynucleotide displacey-linker duplex which is capable of

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initiating branch migration at the end of a recipient polydeoxynucleotde duplex without the prior formation of a stable hybrid with such recipient polydeoxynucleotlde duplex as recited in claim 6.

Regarding claim 24, Maniatis *et al.*, teach the artificially constructed polydeoxynucleotide hybrid of any of claims 6-22 (ie., EcoRI digested charon 4A vector) wherein the linker strand (ie., a strand having a EcoRI 4 bp cohesive end in the EcoRI digested charon 4A vector) is covalently linked to one of the strands of the recipient duplex (ie., a strand without a EcoRI 4 bp cohesive end in the EcoRI digested 20 kb eukaryotic genomic DNA) after ligation reaction.

Regarding claim 148, since Maniatis *et al.*, teach to clone EcoRI digested 20 kb eukaryotic genomic DNA into EcoRI digested charon 4A vector (see Figure 1 in page 688) and the DNA fragment digested with EcoRI has 4 bp cohesive ends, Maniatis *et al.*, disclose an artificially constructed polynucleotide hybrid comprising a naturally occurring recipient polynucleotide duplex (ie., EcoRI digested 20 kb eukaryotic genomic DNA having 4 bp cohesive ends) hybridized to the displacer-linker duplex of any of claims 118-147 (ie., EcoRI digested charon 4A vector having 4 bp cohesive ends). Note that, since a recipient polynucleotide duplex is not a component of claim 117 and the EcoRI digested charon 4A vector taught by Maniatis *et al.*, has an ability to bind to a recipient polynucleotide duplex which exists in nature and is different from the recipient polynucleotide duplex recited in claim 148, the EcoRI digested charon 4A vector taught by Maniatis *et al.*, is an oligo- or polydeoxynucleotide displacey-linker duplex as recited in claim 117.

Therefore, Maniatis et al., teach all limitations recited in claims 23, 24, and 148.

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Claim Rejections - 35 USC § 103

- 15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 9 and 125 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dattagupta as applied to claims 6-8, 16-18, 22, 117-119, 121, 144, and 145 above, and further in view of Gewirtz *et al.*, (US Patent No. 5,098, 890, priority date: November 7, 1988).

The teachings of Dattagupta have been summarized previously, supra.

Dattagupta does not disclose that at least one of the nucleotides complementary to one strand of the recipient polydeoxynucleotide duplex is modified to increase the stability of the hybrid displacer-recipient duplex as recited in claim 9 and at least one of said nucleotides complementary to one strand of the recipient polynucleotide is modified to increase the stability

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of the displacer-recipient complex, wherein the modification is in the second sequence as recited in claim 125.

Regarding claims 9 and 125, since Gewirtz *et al.*, teach that substituting a methyl group or sulfur atom for a phosphate oxygen in the internucleotide phosphodiester linkage of A, dA, G, dG, C, dC, T, and U of polynucleotide would make polynucleotide more resistant to nuclease digestion (see column 10, lines 59-67 and column 11, lines 1-3), Gewirtz *et al.*, disclose at least one of the nucleotides is modified to increase the stability of the hybrid displacer-recipient duplex as recited in claim 9 and at least one of said nucleotides is modified to increase the stability of the displacer-recipient complex wherein the modification is in the second sequence as recited in claim 125.

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have used made the nucleic acid displacers recited in claims 9 and 125 wherein at least one of the nucleotides complementary to one strand of the recipient polydeoxynucleotide duplex is modified to increase the stability of the hybrid displacer-recipient duplex and at least one of said nucleotides complementary to one strand of the recipient polynucleotide is modified to increase the stability of the displacer-recipient complex and the modification is in the second sequence in view of the prior art of Dattagupta and Gewirtz *et al.*. One having ordinary skill in the art would have been motivated to do so because Gewirtz *et al.*, suggest that substituting a methyl group or sulfur atom for a phosphate oxygen in the internucleotide phosphodiester linkage of A, dA, G, dG, C, dC, T, and U of polynucleotide (modification of one of nucleotide) would make polynucleotide more resistant to nuclease digestion (see column 10, lines 59-67 and column 11, lines 1-3). One having ordinary skill in the

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art at the time the invention was made would have been a reasonable expectation of success to make a the nucleic acid displacer recited in claims 9 and 125 in view of the prior art of Dattagupta and Gewirtz et al..

17. Claims 19-21, 146, and 147 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dattagupta as applied to claims 6-8, 16-18, 22, 117-119, 121, 144, and 145 above, and further in view of Engelhardt *et al.*, (US Patent No. 5,260,433, priority date: June 23, 1982).

The teachings of Dattagupta have been summarized previously, supra.

Dattagupta does not disclose that the displacer-linker duplex of claim 6 which contains a modification which allows capture of the displacer-recipient hybrid by affinity chromatography as recited in claim 19 wherein the modification is selected from the group consisting of biotin moieties and phosphorothioate linkages as recited in claim 20 and the modification is present in the linker as recited in claim 21, and said modification in claim 144 is selected from the group consisting of biotin moieties, phosphorothioate linkages and antigens as recited in claim 146 and a modification which allows capture of the displacer-recipient complex by affinity chromatography as recited in claim 147.

Regarding claims 19-21, 146, and 147, since Engelhardt *et al.*, teach polynucleotides which are chemically modified or labeled such as labeling biotin so as to be capable of ready detection when attached to and/or incorporated in nucleic acid material (see abstract and column 1), Engelhardt *et al.*, disclose a modification (ie., the biotin-label) which allows capture of the displacer-recipient hybrid by affinity chromatography (ie., an affinity column having avidin) as recited in claim 19 wherein the modification is selected from the group consisting of biotin

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moieties and phosphorothioate linkages as recited in claim 20 and the modification is present in the linker as recited in claim 21, and said modification is selected from the group consisting of biotin moieties, phosphorothioate linkages and antigens as recited in claim 146 and a modification (ie., the biotin-label) which allows capture of the displacer-recipient complex by affinity chromatography (ie., an affinity column having avidin) as recited in claim 147.

Therefore, it would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to have used made the nucleic acid displacers recited in claims 19-21, 146 and 147 wherein the displacer-linker duplex of claim 6 which contains a modification which allows capture of the displacer-recipient hybrid by affinity chromatography and the modification is biotin moieties, and the modification is present in the linker and said modification in claim 144 is biotin moieties, and a modification which allows capture of the displacer-recipient complex by affinity chromatography as recited in claim 147 in view of the prior art of Dattagupta and Engelhardt et al.. One having ordinary skill in the art would have been motivated to do so because Engelhardt et al., state that "[B]iotin-labeled polynucleotides, both single and double stranded, are selectively and quantitatively retained on avidin-Sepharose, even after extensive washing with 8M urea, 6M guanidine hydrochloride or 99% formamide. In addition, biotin-labeled nucleotides can be selectively immunoprecipitated in the presence of antibiotin antibody and Staphylococcus aurea, Protein A. These unique features of biotin-labeled polynucleotides suggest that they are useful affinity probes for the detection and isolation of specific DNA and RNA sequences" (see column 1, third paragraph). One having ordinary skill in the art at the time the invention was made would have been a reasonable expectation of success

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to make a the nucleic acid displacers recited in claims 19-21, 146 and 147 in view of the prior art of Dattagupta and Engelhardt *et al.*.

Double Patenting

18. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer <u>cannot</u> overcome a double patenting rejection based upon 35 U.S.C. 101.

19. Claims 6-9 and 11-24 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 6-9 and 11-24 of prior U.S. Patent No. 5,958,681 because claims 6-9 and 11-24 in this instant application are identical to claims 6-9 and 11-24 of U.S. Patent No. 5,958,681. This is a double patenting rejection.

Conclusion

- 20. No claim is allowed.
- 21. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

May 10, 2006

FRANK LU
PRIMARY EXAMINER

George C. Ellott, Ph.D

Director

Technology Center 1600